# Legislative Analysis

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**COMBATTING OPIOID EPIDEMIC**

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**House Bill 4403 (proposed substitute H-1)**
**Sponsor: Rep. Andy Schor**

**House Bill 4404 (proposed H-2)**
**Sponsor: Rep. Sam Singh**

**House Bill 4405(w/ proposed amendment)**
**Sponsor: Rep. Kathy Crawford**

**House Bill 4406 as introduced**
**Sponsor: Rep. Beth Griffin**

**House Bill 4407 (proposed H-1)**
**Sponsor: Rep. Beth Griffin**

**House Bill 4408 (proposed H-1)**
**Sponsor: Rep. Joseph N. Bellino, Jr.**

**Committee: Health Policy**
**Complete to 5-22-17**

**BRIEF SUMMARY:**

House Bills 4403-4408 are part of a larger effort to combat the opioid epidemic in Michigan and nationwide. Taken together, the bills would do all of the following:

- Specifically provide that an individual may receive medically necessary treatment for opioid use. (HB 4403)
- Define and allow for the licensure of pain management facilities by the Department of Licensing and Regulatory Affairs (LARA). (HB 4404)
- Allow a pharmacist to refuse to fill a prescription for a schedule II-V controlled substance, if the pharmacist has a reasonable and good-faith belief that it was not written in good faith or would not be filled for a medical purpose. (HB 4405)
- Require the Prescription Drug and Opioid Abuse Commission to develop recommendations on teaching about opioid abuse in schools. (HB 4406)
- Require the Michigan Department of Education (MDE) to make available a model program of instruction based on those recommendations to school districts and public school academies (PSAs); and to ensure that the model program, at least, is included in the state's Model Core Curriculum content standards and the health education component of the Merit Curriculum graduation requirements. (HB 4407)
- Require a prescriber to discuss certain issues and obtain a signed parental consent form before issuing the first prescription to a minor in a single course of treatment for a controlled substance containing an opioid. The bill would also amend two existing sections to make failure to comply with these requirements a violation punishable by probation, limitation, denial, fine, suspension, revocation, or permanent revocation of the prescriber's license. (HB 4408)

All six bills would take effect 90 days after enactment. House Bills 4406 and 4407 are tie-barred together, meaning neither could take effect unless both are enacted.

**DETAILED SUMMARY:**

## House Bill 4403

House Bill 4403 would amend the section of the Social Welfare Act (MCL 400.109) that describes the medical services which may be provided under the act (the Medicaid program). In addition to services such as certain medical, surgical, nursing home, pharmaceutical, and psychiatric services, among others, the bill would require that an eligible individual may receive **medically necessary acute medical detoxification for opioid use disorder, medically necessary inpatient care at an approved facility, or care in an appropriately licensed substance use disorder treatment facility.**

## House Bill 4404

House Bill 4404 would add a Part 218: Pain Management Facilities (MCL 333.21801 et al.) to the Public Health Code, defining "pain management facilities" and prescribing their establishment, management, and required certification under the Department of Licensing and Regulatory Affairs (LARA). The bill would also amend five sections of the Code to account for this new entity, including the addition of "pain management facilities" to the Code's definition of health facilities or agencies.

The new **Part 218** of the Code would define the following key terms:

- ***Pain management facility***: a facility where a majority of the patients are provided treatment for pain through the use of a controlled substance and either the facility's primary practice is the treatment of pain or the facility advertises for any type of pain management service. (A pain management facility does not include a county medical care facility, hospital or facility that is owned and operated by a hospital, nursing home, or a hospital long-term care unit, among others)
- ***Pain management service***: medical care specializing in managing chronic or acute pain.
- ***Controlled substance*** (as defined in MCL 333.7104): a drug, substance, or immediate precursor included in schedules 1 to 5 of part 72 (Schedule 1: MCL 333.7212; Schedule 2: MCL 333.7214; Schedule 3: MCL 333.7216; Schedule 4: MCL 333.7218; Schedule 5: MCL 333.7220)

Establishing a pain management facility

Under the bill, beginning January 1, 2018, a person must submit a completed application for licensure in order to establish or maintain and operate a pain management facility. Beginning June 1, 2018, a person must have obtained a license from the Department of Licensing and Regulatory Affairs in order to establish or maintain and operate the facility.

Ownership of a pain management facility

Generally, an individual who is not a physician may not have an ownership interest in a pain management facility. However, this prohibition does not apply for a facility operating as of the effective date of the act so long as no individual employed by the facility or the

facility itself has been sanctioned by a disciplinary committee under the Code for an act or omission involving a controlled substance, and no employee has a controlled substance conviction.

If one of the owners of a pain management facility operating when this act takes effect is not a physician, the facility's owners must designate a physician employed by the facility as its designated physician, with the requirements for that role described below.

Designated physician

Beginning one year after the act takes effect, the owners of the pain management facility must ensure that a designated physician or at least one physician who has an ownership interest in the pain management be physically present in the practice of medicine or osteopathic medicine and surgery, for at least 50% of the time a patient is present at the facility. These physicians must also meet one of the following:

- Hold a subspecialty certification in pain management or hospice and palliative medicine issued by the American Board of Medical Specialties, a certificate of added qualification in pain management or hospice and palliative medicine issued by the American Osteopathic Association Bureau of Osteopathic Specialists, or an equivalent certification or certificate as determined by LARA.
- Hold a board certification issued by the American Board of Pain Management, the American Board of Interventional Pain Physicians, or an equivalent certification as determined by LARA.
- Have completed a residency or fellowship in pain management approved by LARA or meet any other educational standard as determined by LARA.

Payment for services

A pain management facility may only accept payment for a good or service provided to a patient from the patient or patient's insurer, guarantor, spouse, parent, legal guardian, or legal custodian. A facility may also accept private health insurance as a source of payment.

Additional Changes

The bill would make complementary amendments to five sections of the Code:

- Add "a pain management facility" to the list of health facilities or agencies under Section 20106 of the Code.
- Require that applicants or licensees to become pain management facilities under Part 218 of the Code must comply with the same disclosure requirements as applicants or licensees to be homes for the aged (Part 213) or nursing homes (Part 217).
- Set the fee for licensure as a pain management facility at $1,000 per facility license, with an initial licensure application fee of $2,000 per initial license.
- Replace references to the Department of Community of Health with the reorganized and renamed Department of Health and Human Services.

## House Bill 4405

House Bill 4405 would amend the Public Health Code (Proposed MCL 333.17751a) to **allow a pharmacist to refuse to dispense a prescription for a controlled substance** listed in schedules two to five in Part 72 of the Code, if the pharmacist has a reasonable and good-faith belief that the prescription was not written in good faith or would not be used for a medical purpose. A pharmacist who does refuse to dispense the prescription will not be held liable for damages in a civil action for injury, death, or loss to person or property arising from that refusal.

## House Bill 4406

House Bill 4406 would add a section to the Public Health Code (proposed MCL 333.7113a), which would **require the Prescription Drug and Opioid Abuse Commission to develop and provide recommendations for the instruction of students on prescription opioid drug abuse** to the Michigan Department of Education (MDE) by January 1, 2018. These must include recommendations for instruction on the prescription drug epidemic and the connection between prescription drug epidemic and the connection between prescription opioid drug abuse and addiction to other drugs.

[The Commission, created within the Michigan Department of Licensing and Regulatory Affairs (LARA) by Governor Snyder's Executive Order No. 2016-15,[1] replaced the Controlled Substances Advisory Commission and the Advisory Committee on Pain and Symptom Management. It was charged with reviewing the 2015 Report of Findings and Recommendations for Action from the Michigan Prescription Drug and Opioid Abuse Task Force, and developing and proposing policies to implement those recommendations, among other tasks.]

## House Bill 4407

House Bill 4407 would add a section to the Revised School Code (proposed MCL 380.1170b) that would require the MDE to **make available to school districts and public school academies (PSAs, or charter schools) a model program of instruction on prescription opioid drug abuse** based on the recommendations from the Commission, above, no later than July 1, 2018. This program must at least include instruction on the prescription drug epidemic and the connection between prescription opioid abuse and addiction to other drugs.

Additionally, the MDE must **ensure that the state's Model Core Curriculum content standards and subject area content expectations and guidelines for health education under Section 1278a[2] of the Code include instruction on prescription opioid drug abuse**, including, at least, the model program of instruction described above. These changes must be in place beginning in the 2018-2019 school year.

[1] https://www.michigan.gov/documents/snyder/EO_2016-15_527251_7.pdf

[2] MCL 380.1278a lists the requirements for a high school diploma, including one credit of health and physical education

[According to the MDE, opioid abuse prevention would be taught within the context of the Michigan Model for Health™ (MMH), an evidence-based curriculum recognized by the Substance Abuse and Mental Health Services Administration (SAHMSA) and listed on their National Registry of Effective and Promising Programs. The MMH curriculum includes existing lessons on substance abuse prevention for every grade level that can be built upon as recommendations from the Commission warrant.]

## House Bill 4408

House Bill 4408 would add a section to the Public Health Code to require a prescriber[3] to discuss certain issues and obtain a signed parental consent form before issuing the first prescription to a minor in a single course of treatment for a controlled substance containing an opioid. The bill would also amend two existing sections to make failure to comply with these requirements a violation punishable by probation, limitation, denial, fine, suspension, revocation, or permanent revocation of the prescriber's license.

Specifically, with some exceptions described later, the bill would require a prescriber to do both of the following:

**Discuss all of the following with a minor and parent or guardian or another adult authorized to consent to the minor's medical treatment, before issuing the minor the first prescription in a single course of treatment for a controlled substance containing an opioid, regardless of whether the physician modifies the dose during the course of treatment:

- The risks of addiction and overdose associated with the controlled substance.
- The increased risk of addiction to a controlled substance for an individual suffering from both mental and substance abuse disorders.
- The danger of taking a controlled substance containing an opioid with a benzodiazepine, alcohol, or another central nervous system depressant.
- Any other information in the patient counseling information section of the label for the controlled substance that is required in paragraph (c)(18) of Part 201 (Labeling) of the Code of Federal Regulations (including information necessary in order for the patient to take the drug safely and effectively).

**Obtain the signature of the minor's parent or guardian on a *Start Talking* consent form. Another adult authorized to consent to the minor's medical treatment may also sign the form, but in that case the prescriber may only prescribe up to a single 72-hour supply of the controlled substance. The prescriber must include the signed form in the minor's medical record.

[3] "***Prescriber***" is defined in section 17708 of the Public Health Code as a licensed dentist, a licensed doctor of medicine, a licensed doctor of osteopathic medicine and surgery, a licensed doctor of podiatric medicine and surgery, a licensed optometrist certified under Part 174 to administer and prescribe therapeutic pharmaceutical agents, a licensed veterinarian, or another licensed health professional acting under the delegation and using, recording, or otherwise indicating the name of the delegating licensed doctor of medicine or licensed doctor of osteopathic medicine and surgery.

***Exemptions***
These requirements do not apply in any of the following circumstances:

- If the minor's treatment is associated with or incident to a medical emergency.
- If the minor's treatment is associated with or incident to a surgery, regardless of whether the surgery is performed on an inpatient or outpatient basis.
- If, in the prescriber's professional judgment, fulfilling the requirements would be detrimental to the minor's health or safety.
- If the minor's treatment is rendered in a hospice or oncology department of a hospital, or if the prescription is issued at the time of discharge from one of those facilities.
- If the consent of the minor's parent or guardian is not legally required for the minor to obtain treatment.

***Definitions***
The bill also defines all of the following terms, as used in this section:

A ***Start Talking consent form*** must be a separate document from any other document that a prescriber uses to obtain informed consent and must contain all of the following:

- The name and quantity of the controlled substance being prescribed for the minor and the amount of the initial dose.
- A statement indicating that a controlled substance is a drug or other substance that the U.S. Drug Enforcement Administration has identified as having a potential for abuse.
- A statement certifying that the prescriber discussed with the minor, and with the minor's parent, guardian or authorized adult, the topics described above.
- The number of refills, if any, that are authorized by the prescription.
- A space for the signature of the minor's parent, guardian, or authorized adult to consent to the minor's medical treatment, and a space for the date signed.

***Another adult authorized to consent to the minor's medical treatment*** means an adult to whom a minor's parent or guardian has given written authorization to consent to the minor's medical treatment.

***Medical emergency*** means a situation that, in the prescriber's good-faith medical judgment, creates an immediate threat of serious risk to the life or physical health of the minor.

***Minor*** means an individual under 18 years old who is not emancipated.

Finally, the bill would include failure to comply with these requirements (discussing the topics listed above with the minor and parent, guardian, or authorized adult; and obtaining a signed consent form) among violations of the Code under Section 16221. The Department of Licensing and Regulatory Affairs (LARA) would investigate allegations of

violation as it does for the 21 offenses currently listed in that section. If the allegations are substantiated, the prescriber would be subject to probation, limitation, denial, fine, suspension, revocation, or permanent revocation of his or her license by a disciplinary subcommittee.

MCL 333.16221 and 333.16226 and proposed 333.7303b

**BACKGROUND INFORMATION:**

Michigan's October 2015 Prescription Drug & Opioid Abuse Task Force report[4] included a series of findings and recommendations. One of the recommendations is incorporated into HB 4405: the task force recommended an exemption from civil liability for a pharmacist acting in good faith and with a reasonable doubt that the prescription is not authentic or would be used for non-medical purposes.

While pharmacists are already allowed to refuse to fill prescriptions for these reasons, they do not have any protection when they choose to do so. The bill would protect a pharmacist from liability, giving pharmacists greater flexibility to use their judgment when it appears a person is doctor- or pharmacy-shopping, or filling more prescriptions for controlled substances than are reasonably needed.

Although the task force report recommended that the exemption "should require consultation with the prescribing physician before the pharmacist can decide to deny filling the prescription[,]" the bill does not include that requirement.

**FISCAL IMPACT:**

House Bill 4403 should have no fiscal impact as these services are already covered under Medicaid.

House Bill 4404 would create significant, though indeterminate, fiscal impacts for the Department of Licensing and Regulatory Affairs. Under the bill, the Department would assess an initial license fee of $2,000.00 and an annual fee of $1,000.00 for pain management facilities. It is currently unknown how many pain management facilities will be applying for licensure in Michigan, so an estimate of total expected revenues from license fees is unattainable. The Department does not anticipate that the expansion of health facilities licensing activities to include pain management facilities will result in significant costs to the Department at present, though if license application volumes are high additional staff may be needed to process applications.

House Bill 4405 would not have a fiscal impact on the Department of Licensing and Regulatory Affairs or on other units of state or local government.

House Bill 4406 would not result in any significant fiscal impacts for the Department of Licensing and Regulatory Affairs or for other units of state and local government.

[4] http://www.michigan.gov/documents/snyder/Presciption_Drug_and_Opioid_Task_Force_Report_504140_7.pdf

House Bill 4407 would result in a cost increase for the Department of Education and an indeterminate cost increase for school districts and public school academies (PSAs). The Department of Education has noted they would incur an estimated cost increase of $250,000 for administrative resources in making available a grade- and age-appropriate model program of instruction on prescription opioid drug abuse to school districts and PSAs. School districts and PSAs would then incur an indeterminate cost increase, at least initially, for administrative resources to include the revised model core academic curriculum content standards for health education and the subject area content expectations and guidelines for health education to include instruction on prescription opioid drug abuse.

House Bill 4408 would not create any significant fiscal impact for the Department of Licensing and Regulatory Affairs or for other units of state or local government.

HB 4408 would have an indeterminate fiscal impact on the state's correctional system and on local units of government. Information is not available on the number of persons that might be found in violation and subsequently convicted under provisions of the bill. New felony convictions would result in increased costs related to state prisons and state probation supervision. In fiscal year 2016, the average cost of prison incarceration in a state facility was roughly $36,000 per prisoner, a figure that includes various fixed administrative and operational costs. State costs for parole and felony probation supervision averaged about $3,500 per supervised offender in the same year. New misdemeanor convictions would increase costs related to county jails and/or local misdemeanor probation supervision. The costs of local incarceration in a county jail and local misdemeanor probation supervision vary by jurisdiction. The fiscal impact on local court systems would depend on how court caseloads were affected and on related administrative costs. Any increases in penal fine revenues would increase funding for local libraries, which are the constitutionally designated recipients of those revenues.

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